

## REMARKS

Claims 1-49 were examined and reported in the Office Action. Claims 1-49 are rejected. Claims 1, 7, 8, 17, 18, 20, 23, 24, 30, 31, 33, 34, 41, 42 and 44-47 are amended for clarification purposes as discussed during a telephone conference with Examiner Roy on June 13, 2006. Claims 1-49 remain.

Applicant requests reconsideration of the application in view of the following remarks.

### **I. 35 U.S.C. §112, first paragraph**

It is asserted in the Office Action that claims 1-49 are rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. Applicant notes that the information of the plurality of target markers is stored so an MRI system can use the information to detect the target markers and not disregard the low level signals from the target markers. The information must be stored before a medical device having these markers is inserted into an anatomy. Therefore, Applicant has amended independent claims 1, 8, 23, 34, 45 and 47 to clarify the claimed invention.

Accordingly, withdrawal of the §112, first paragraph rejections for claims 1-49 are respectfully requested.

### **II. 35 U.S.C. §112, Second Paragraph**

It is asserted in the Office Action that claims 1-49 are rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Applicant has amended independent claims 1, 8, 23, 34, 45 and 47 to overcome the 35 U.S.C. §112, second paragraph rejections.

Accordingly, withdrawal of the 35 U.S.C. §112, second paragraph rejections for claims 1-49 are respectfully requested.

### III. 35 U.S.C. § 102(e)

It is asserted in the Office Action that claims 1, 4-10, 13-24, 27-35 and 38-49 are rejected under 35 U.S.C. § 102(b), as being anticipated by U.S. Patent No. 6,272,370 issued to Gillies et al. ("Gillies"). Applicant respectfully traverses the aforementioned rejection for the following reasons.

According to MPEP §2131,

'[a] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.' (Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987)). 'The identical invention must be shown in as complete detail as is contained in the ... claim.' (Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989)). The elements must be arranged as required by the claim, but this is not an ipsissimis verbis test, *i.e.*, identity of terminology is not required. (In re Bond, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990)).

Applicant's amended claim 1 contains the limitations of

a medical device adapted to be inserted in an anatomy, the medical device comprising a plurality of target markers, information for the plurality of target markers is stored in a magnetic resonance imaging (MRI) system prior to insertion of the medical device into the anatomy, wherein the MRI system is unable to detect or will disregard the target markers as noise without using the stored information for the plurality of target markers to lower a detection threshold of the MRI system.

Applicant's amended claim 8 contains the limitations of

a magnetic resonance imaging (MRI) processor, the processor including a low-level signal detection process stored in a memory, a MRI scanner coupled to the processor, a control unit coupled to the processor, a display coupled to the processor, and a medical device to insert in an anatomy, the medical device having a plurality of target markers, information for the plurality of target markers is stored in the memory prior to insertion of the medical device into the anatomy, wherein the plurality of target markers are not detectable or disregarable as noise for MRI systems without

the low-level signal detection process and without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower a signal detection threshold.

Applicant's amended claim 23 contains the limitations of

inserting a medical device into an anatomy, the medical device having a plurality of target markers, storing information for the plurality of target markers in a memory prior to insertion of the medical device into the anatomy, scanning a magnetic resonance image (MRI) of the anatomy, processing the scanned image by a MRI processor coupled to the memory, determining a location and orientation of the medical device in relation to the anatomy based on the plurality of target markers, and displaying a precise image of the medical device within the anatomy, wherein the plurality of target markers are disregarable as noise or undetectable for MRI systems without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower a signal detection threshold.

Applicant's amended claim 34 contains the limitations of

storing information for the plurality of target markers in a memory prior to insertion of the medical device into an anatomy, scanning a magnetic resonance image (MRI) of an anatomy, processing the scanned image by a MRI processor coupled to the memory, the MRI processor having a low-level signal detection process, determining a location and orientation of the medical device in relation to the anatomy based on a plurality of target markers, and displaying a precise image of the medical device within the anatomy, wherein the plurality of target markers are not detectable or disregarable as noise for MRI systems without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower a signal detection threshold.

Applicant's amended claim 45 contains the limitations of

storing information for a plurality of target markers in a memory prior to insertion of a medical device into an anatomy, scanning a magnetic resonance image (MRI) of the anatomy, processing the scanned image by a MRI processor coupled to the memory, the MRI processor having a low-level signal detection process, determining a location and orientation of the medical device in

relation to the anatomy based on detection of a plurality of target markers in relation to the medical device and each of the plurality of target markers, wherein the plurality of target markers and geometric data of the medical device is stored before the medical device is inserted into the anatomy, and displaying a precise image of the medical device within the anatomy, wherein the plurality of target markers are not detectable or disregardable as noise for MRI systems without the low-level signal detection process and without using the information of the plurality of target markers to lower a signal detection threshold.

Applicant's amended claim 47 contains the limitations of

a magnetic resonance imaging (MRI) processor, the processor including a low-level signal detection process stored in a memory, a MRI scanner coupled to the processor, a control unit coupled to the processor, a display coupled to the processor, and a medical device to insert in an anatomy, the medical device having a plurality of target markers, detection information for the plurality of target markers are stored in the memory prior to insertion of the medical device into the anatomy, the plurality of target markers are not detectable or disregardable as noise for MRI systems without the low-level signal detection process and without using the stored detection information of the plurality of target markers to lower a signal detection threshold, and location and orientation of the medical device in relation to the anatomy is determined by the processor based on detection of the plurality of target markers in relation to the geometric information of the medical device and each of the plurality of target markers, wherein the geometric information of the medical device and the plurality of the target markers is stored before the medical device is inserted into the anatomy.

In other words, Applicant's claimed invention includes target markers on a medical device that are undetectable or disregarded as noise by an MRI system if the MRI system does not first have information relating to the target markers to lower a signal detection threshold before the medical device is used in a procedure and inserted into an anatomy.

Gillies discloses a device and method for targeted drug delivery. The device disclosed in Gillies is "MR-visible." (See Gillies, Title; column 10, lines 56-61). The device includes a magnetic tip. In another embodiment, Gillies discloses an MR-visible microdialysis probe. (See Gillies, column 13, lines 37-42). Nowhere in Gillies is an insertable medical device disclosed

having a plurality of target markers that are undetectable or, by having such a low signal, would be disregarded as noise. And, nowhere in Gillies is it taught, disclosed or suggested (or even mentioned) that prior to insertion of the medical device, information of the target markers is stored so the MRI system would be able to lower its signal detection threshold. It is asserted in the Office Action that Gillies, at column 11, lines 5-38, discloses a pre-operative scan is conducted of the markers. These markers, however, are not on a medical device. These are markers placed on a person's skull. (Gillies, column 11, lines 5-11). The markers disclosed in Gillies are both MR and x-ray visible. (Gillies, column 11, lines 3 – 5). After the pre-operative scan is completed, Gillies discloses storing the array of images taken. (Gillies, column 11, lines 11-13).

Gillies, however, does not teach, disclose or suggest the limitations in: claim 1 of

information for the plurality of target markers is stored in a magnetic resonance imaging (MRI) system prior to insertion of the medical device into the anatomy, wherein the MRI system is unable to detect or will disregard the target markers as noise without using the stored information for the plurality of target markers to lower a detection threshold of the MRI system,

in claim 8 of

information for the plurality of target markers is stored in the memory prior to insertion of the medical device into the anatomy, wherein the plurality of target markers are not detectable or disregardable as noise for MRI systems without the low-level signal detection process and without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower a signal detection threshold,

in claim 23 of

storing information for the plurality of target markers in a memory prior to insertion of the medical device into the anatomy, ... the plurality of target markers are disregardable as noise or undetectable for MRI systems without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower a signal detection threshold,

in claim 34 of

storing information for the plurality of target markers in a memory prior to insertion of the medical device into an anatomy, ... the plurality of target markers are not detectable or disregardable as noise for MRI systems without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower a signal detection threshold,

in claim 45 of

storing information for a plurality of target markers in a memory prior to insertion of a medical device into an anatomy, ... wherein the plurality of target markers are not detectable or disregardable as noise for MRI systems without the low-level signal detection process and without using the information of the plurality of target markers to lower a signal detection threshold.

and in claim 47 of

detection information for the plurality of target markers are stored in the memory prior to insertion of the medical device into the anatomy, the plurality of target markers are not detectable or disregardable as noise for MRI systems without the low-level signal detection process and without using the stored detection information of the plurality of target markers to lower a signal detection threshold.

Therefore, since Gillies does not disclose, teach or suggest all of Applicant's amended claims 1, 8, 23, 34, 45 and 47 limitations, Applicant respectfully asserts that a *prima facie* rejection under 35 U.S.C. § 102(e) has not been adequately set forth relative to Gillies. Thus, Applicant's amended claims 1, 8, 23, 34, 45 and 47 are not anticipated by Gillies. Additionally, the claims that directly or indirectly depend on claims 1, 8, 23, 34, 45 and 47, namely claims 4 and 7, 9-10 and 13-22, 24 and 27-33, 35 and 38-44, 46, and 48-49, respectively, are also not anticipated by Gillies for the same reason.

Accordingly, withdrawal of the 35 U.S.C. § 102(e) rejections for claims 1, 4-10, 13-24, 27-35 and 38-49 are respectfully requested.

**IV. 35 U.S.C. § 103**

It is asserted in the Office Action that Claims 2, 3, 11, 12, 25, 26, and 37 are rejected in the Office Action under 35 U.S.C. § 103(a), as being unpatentable over Gillies in view of U.S. Patent No. 5,817,017 issued to Young et al. ("Young"). Applicant respectfully traverses the aforementioned rejection for the following reasons.

According to MPEP §2142

[t]o establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. (In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)).

Further, according to MPEP §2143.03, "[t]o establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. (In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974))." "*All words in a claim must be considered in judging the patentability of that claim against the prior art.*" (In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970), emphasis added.)

Claims 2 and 3 depend on amended claim 1. Claims 11-12 depend on amended claim 8. Claims 25-26 depend on amended claim 23. Claim 37 depends on amended claim 34. Applicant has addressed Gillies regarding amended claims 1, 8, 23 and 34 above in section III.

Young discloses a medical device that includes ionic particles incorporated throughout the medical device. The amount of the particles is such that detection of the device through magnetic imaging is enhanced. That is, the amount of particles will never be disregarded as noise or undetectable. Further, no information on the ionic particles need be obtained before Young's device is inserted, as the device will be visible in magnetic imaging.

It is asserted in the Office Action that Young discloses paramagnetic material to enhance MR visibility. If the paramagnetic particles are used to enhance visibility, then the markers cannot be either undetectable or disregarded as noise. Therefore, Young does not teach, disclose or suggest the limitations contained in: claim 1 of

information for the plurality of target markers is stored in a magnetic resonance imaging (MRI) system prior to insertion of the medical device into the anatomy, wherein the MRI system is unable to detect or will disregard the target markers as noise without using the stored information for the plurality of target markers to lower a detection threshold of the MRI system,

in claim 8 of

information for the plurality of target markers is stored in the memory prior to insertion of the medical device into the anatomy, wherein the plurality of target markers are not detectable or disregardable as noise for MRI systems without the low-level signal detection process and without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower a signal detection threshold,

in claim 23 of

storing information for the plurality of target markers in a memory prior to insertion of the medical device into the anatomy, ... the plurality of target markers are disregardable as noise or undetectable for MRI systems without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower a signal detection threshold,

and in claim 34 of

storing information for the plurality of target markers in a memory prior to insertion of the medical device into an anatomy, ... the plurality of target markers are not detectable or disregardable as noise for MRI systems without using the stored information of the plurality of target markers prior to insertion of the medical device into the anatomy to lower a signal detection threshold.

Therefore, even if Gillies were combined with Young, the resulting invention would still not include all of Applicant's claimed limitations. Moreover, since neither Young nor Gillies teach, disclose or suggest all the limitations of Applicant's amended claims 1, 8, 23 and 34,



Applicant's amended claims 1, 8, 23 and 34 are not obvious over Gillies in view of Young since a *prima facie* case of obviousness has not been met under MPEP §2142. Additionally, the claims that directly or indirectly depend from amended claims 1, 8, 23 and 34, namely claims 2 and 3, 11 and 12, 25 and 26, and 36-37, respectively, would also not be obvious over Gillies in view of Young for the same reason.

Accordingly, withdrawal of the 35 U.S.C. § 103(a) rejections for Claims 1, 8, 23 and 34 are respectfully requested.

**CONCLUSION**

In view of the foregoing, it is submitted that claims 1-49 patentably define the subject invention over the cited references of record, and are in condition for allowance and such action is earnestly solicited at the earliest possible date. If the Examiner believes a telephone conference would be useful in moving the case forward, he is encouraged to contact the undersigned at (310) 207-3800.

If necessary, the Commissioner is hereby authorized in this, concurrent and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2666 for any additional fees required under 37 C.F.R. §§1.16 or 1.17, particularly, extension of time fees.

Respectfully submitted,

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Jean Svoboda